**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF OHIO**
**EASTERN DIVISION**

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| IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION<br><br>This document relates to:<br>*County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.*<br>Case No. 1:18-OP-45090<br><br>*The County of Cuyahoga v. Purdue Pharma L.P., et al.*<br>Case No. 1:17-OP-45004 | MDL No. 2804<br><br>Case No. 17-md-2804<br><br>Hon. Dan Aaron Polster |

**MANUFACTURER DEFENDANTS' BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT FOR PLAINTIFFS' FAILURE TO OFFER PROOF OF CAUSATION**

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## INTRODUCTION

To survive summary judgment, Plaintiffs must have evidence that each Manufacturer Defendant's alleged misconduct proximately caused the harms for which Plaintiffs seek relief. *See* Dkt. 1203 at 10. At the pleading stage, the Court suggested that Plaintiffs could potentially establish proximate causation by showing (i) that Manufacturer Defendants' alleged deceptive marketing and distribution control failures caused doctors in the Track One Counties to prescribe more opioids than were medically necessary, (ii) that those excess opioids were diverted into a black market, and (iii) that Plaintiffs have spent and will continue to spend money to address problems caused by those excess opioids. *Id*. at 9–10.

The Manufacturer Defendants disagree that the above would be legally sufficient to prove causation in light of the intervening and superseding causes in this record, but that debate is now academic. With discovery now substantially complete, Plaintiffs have no proof that any Manufacturer Defendant engaged in unlawful conduct that resulted in "more opioids than the legitimate medical market could support" in Cuyahoga or Summit County. *See id.* Indeed, Plaintiffs have made no effort to establish that doctors wrote more prescriptions in the Track One Counties than were medically necessary, let alone that any allegedly unnecessary prescriptions stem from unlawful conduct by any Manufacturer Defendant.

As proof of causation, Plaintiffs rely almost exclusively on the opinions of two experts: Professor Meredith Rosenthal and Professor David Cutler. Whether or not these experts' opinions are admissible (they are not, for the reasons addressed separately in *Daubert* motions), they cannot establish proximate causation because, even if the Court admits these experts and takes their opinions as true, they fundamentally address the wrong question. The right question is whether each Manufacturer Defendant's alleged misconduct (*i.e.*, deceptive marketing or distribution-control failures) proximately caused the harms for which Plaintiffs seek relief. But Rosenthal and

Cutler answered different questions. Collectively, their models purport to show that all detailing by Manufacturer Defendants and non-defendants alike (visits to health care providers by manufacturer sales representatives) led to an increase in total shipments of prescription opioid medicines (not just Manufacturers' medicines or shipments), which in turn led to an increase in mortality from legal and illegal opioids like heroin and fentanyl.

This approach fails for several reasons. As a threshold matter, Plaintiffs' experts made no attempt to measure the effect of the alleged misconduct. Detailing is not unlawful, yet Rosenthal does nothing to separate the impact of ***lawful*** promotional activities from any ***allegedly unlawful*** promotional activities. She simply assumes that all detailing was uniformly unlawful. Put another way, she purports to address the effects of ***all*** prescription opioid medicine detailing, not of the alleged ***deceptive*** promotion. Nor does she attempt to identify, isolate, or quantify medically unnecessary or excess prescriptions caused by the detailing she analyzed. And neither Rosenthal nor any other expert identifies, quantifies, or attempts to measure whether and to what extent there were any "excess" opioid orders or shipments caused by any Manufacturer Defendant's alleged distribution-control failures.

While Rosenthal fails to analyze the relevant conduct, Cutler relies on that flawed analysis and separately fails to analyze the relevant harm or link any harms to the alleged misconduct. Cutler assesses the relationship between all shipments of prescription opioid medications nationwide—from both Manufacturer Defendants' and non-defendants', whether allegedly unlawful or not—and mortality from all opioids, including illegal drugs like heroin and street fentanyl. Yet there is no legal or factual basis for holding Manufacturer Defendants liable for harms caused by illicit drugs. Nonetheless, Plaintiffs have given the trier of fact no way to carve those harms out of their models to determine which, if any, of the alleged harms were caused

by the "excess" sale of Manufacturer Defendants' medicines. And no reasonable juror could find the manufacturers of prescription opioid medications legally responsible for the effects of criminal drug trafficking on the record in this case.

Plaintiffs' aggregate models also improperly lump together all the Manufacturer Defendants' medications and all the alleged misconduct, with no attempt to separate out what any particular Manufacturer did wrong or what harm resulted from that alleged wrongdoing. When Plaintiffs resisted individualized discovery, choosing instead to rely solely on "aggregate proof," Special Master Cohen cautioned that "the requisite level of proof [of causation] is an issue the Court may have to answer at a future stage of litigation, perhaps through orders resolving summary judgment or *Daubert* motions," and "if Plaintiffs are incorrect" that their aggregate proof is sufficient to prove causation, "Defendants will rightly point to Plaintiffs' [discovery responses] as a basis for defense judgment." ECF No. 606 at 4-5. That is precisely what has come to pass. Plaintiffs have no evidence that their alleged injuries were proximately caused by the collective "Manufacturers," much less proximately caused by ***each Manufacturer***—rather than by criminal cartels trafficking in deadly street drugs.

Plaintiffs base their case solely on theoretical regression analyses unmoored from any facts that could establish a causal chain. They are thus left with a far more complex and inappropriate version of the general statistical evidence that federal appellate courts have repeatedly rejected. Allowing this case to proceed to trial would be unprecedented and would contravene bedrock principles of tort law. Manufacturer Defendants are entitled to summary judgment on all claims.

## ARGUMENT

### I. ALL OF PLAINTIFFS' CLAIMS REQUIRE PROOF OF PROXIMATE CAUSATION.

Plaintiffs allege that by fraudulently marketing their prescription opioid medicines and failing to use proper controls to stop diversion of those medicines, Manufacturers caused Plaintiffs to suffer immense "costs associated with responding to and working to stem the opioid epidemic." ECF No. 1025 (Ruiz R&R) at 27. Based on these theories, Plaintiffs plead claims for a marketing enterprise and a supply-chain enterprise under the Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. §§ 1961 *et seq.* (Counts 1-2); two analogous claims under the Ohio Corrupt Practices Act (OCPA), Ohio Rev. Code §§ 2923.31 *et seq.* (Counts 3-4); claims for statutory and absolute common law public nuisance (Counts 5-6); Ohio common law claims for negligence (Count 7); fraud (Count 8);[1] unjust enrichment (Count 10); civil conspiracy (Count 11); and injury through criminal acts under Ohio Rev. Code § 2307.60 (Count 9). Each of these counts shares a fundamental legal element—Plaintiffs must prove that the unlawful conduct they challenge proximately caused the harm for which they seek damages or abatement costs.[2]

### II. PLAINTIFFS' EVIDENCE CANNOT SATISFY THEIR BURDEN TO PROVE CAUSATION.

With discovery substantially complete, Plaintiffs cannot prove proximate cause because they have failed to develop the evidence necessary to prove that the Manufacturers' alleged

[1] On June 25, 2019, Plaintiffs represented to the Court that they will dismiss their fraud claim. They have yet to formally dismiss the claim, however, and Manufacturer Defendants request that they do so promptly.

[2] *See, e.g.*, *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 268 (1992) (RICO); *City of Cleveland v. Ameriquest Mortg. Secs., Inc.*, 615 F.3d 496, 502 (6th Cir. 2010) (OCPA); *City of Cincinnati v. Deutsche Bank Nat'l Tr. Co.*, 863 F.3d 474, 480 (6th Cir. 2017) (public nuisance); *Berisford v. Sells*, 331 N.E.2d 408, 409 (Ohio 1975) (negligence); *Picklesimer v. Balt. & O. R. Co.*, 84 N.E.2d 214, 217 (Ohio 1949) (fraud); *Jacobson v. Kaforey*, 75 N.E.3d 203, 206 (Ohio 2016) (injury through criminal acts); *Robinson v. Vehicle Acceptance Corp.*, No. 105006, 2017 WL 3084579, at *4 (Ohio App. July 20, 2017) (unjust enrichment); *Lawyers Title Co., LLC v. Kingdom Title Sols., Inc.*, 592 F. App'x 345, 355 (6th Cir. 2014) (civil conspiracy); *see also* Restatement (Second) of Torts § 430 (1965). The Court has held that only injunctive relief is available for Plaintiffs' statutory public nuisance claim. *See* ECF No. 1203 at 31.

unlawful conduct (collectively or individually) caused Plaintiffs' harms. In ruling on motions to dismiss, the Court identified a possible chain of proximate causation from Plaintiffs' allegations: (i) Manufacturers "made deceptive claims in promoting their opioids in order to sell more opioids than the legitimate medical market could support"; (ii) "the excess opioids marketed by [Manufacturers] and distributed by [Manufacturers and Distributors] were then diverted into an illicit, black market"; and (iii) "Plaintiffs were forced to expend resources beyond what they had budgeted to attempt to stop the flow of the excess opioids into local communities and to bear the costs associated with cleaning them up." ECF No. 1203 at 9-10.

Although the actual causal chain requires a number of additional steps (which involve numerous superseding and intervening causes),[3] Plaintiffs have failed to develop proof even of those elements of causation highlighted by the Court. Specifically, the aggregate models offered by Plaintiffs' experts do not even purport to answer the questions emphasized by the Court, including (a) what, if any, medically improper/excess prescription opioids were caused by Manufacturers' alleged false marketing; (b) what, if any, excess prescription opioids that were diverted into black markets were caused by Manufacturers' alleged distribution-control failures; (c) whether pharmaceutical marketing somehow caused diversion; or (d) what amount of Plaintiffs' harms, if any, were caused by any medically improper/excess opioid prescriptions. Nor do they address the impact (if any) that each individual Manufacturer Defendant (or the predicate acts of any alleged conspiracy) had on Plaintiffs' alleged harms. Plaintiffs' decision to rely solely

[3] As Manufacturer Defendants articulated previously, the chain of causation from the alleged fraudulent marketing to Plaintiffs' injuries includes the following steps: (i) a Manufacturer made deceptive claims in promoting its opioids (the conduct); (ii) some physicians were exposed to that Manufacturer's claims; (iii) which caused some of those physicians to write medically inappropriate opioid prescriptions they would not have otherwise written; (iv) which caused some of their patients to decide to take opioids; (v) which caused some of those individuals to become addicted to opioids; (vi) which caused some of those addicted individuals to need additional medical treatment, to neglect or abuse their families, to lose their jobs, and/or to commit crimes; (vii) which caused Plaintiffs to expend additional resources on emergency services, and to lose revenue from a decreased working population and/or diminished property values (the injury). *See* ECF No. 1203 at 9.

on statistics and expert testimony to prove causation, coupled with their experts' failure to analyze the relevant causal questions, is fatal to Plaintiffs' ability to prove their claims.

### A. Plaintiffs Have No Evidence That Any Manufacturer's Allegedly Fraudulent Marketing Proximately Caused Their Alleged Injuries.

#### *1. Plaintiffs Cannot Prove Any Manufacturer's Allegedly Fraudulent Marketing Caused Medically Unnecessary or Excess Prescriptions.*

To succeed on their claims that are based on Manufacturers' purported fraudulent marketing (Counts 1, 3, 5-11), Plaintiffs must present evidence of the foundational first step in the causal chain—that the alleged false marketing statements caused medically unnecessary/excess prescriptions. This causal relationship is predicated on prescribers' reliance on Manufacturers' allegedly false marketing.[4] For this part of the causal chain, Plaintiffs rely almost exclusively on the analysis of their expert, Meredith Rosenthal. Rosenthal's testimony is fundamentally flawed and should be excluded for the reasons explained in the accompanying *Daubert* motion. But even if it is admitted in its entirety, Rosenthal's testimony provides no evidence that the Manufacturers' alleged false marketing (collectively or individually) caused improper/excess prescribing because Plaintiffs asked her to analyze the wrong questions.

Plaintiffs asked Rosenthal to determine whether the promotion of opioids in general, by both Defendants and non-defendants, since 1995 caused an increase in opioid prescribing and, if so, to what degree. (Ex. 1, Rosenthal Rep. ¶ 8.) To answer these questions, Rosenthal prepared regression analyses supposedly designed to measure the aggregate effect of all prescription opioid

[4] Even if Plaintiffs had not represented to the Court on June 25, 2019, that they will withdraw their Ohio common law fraud claim, they cannot prove it for an additional, related reason. That claim requires evidence that Plaintiffs' injuries were proximately caused by *their own* justifiable reliance on a materially false statement. *See, e.g.*, *Aetna Cas. & Sur. Co. v. Leahey Const. Co.*, 219 F.3d 519, 540 (6th Cir. 2000); *Lucarell v. Nationwide Mut. Ins. Co.*, 97 N.E.3d 458, 472 (Ohio 2018). In other words, Plaintiffs must prove not only that they justifiably relied on the specific false statement(s) alleged, but also that such reliance proximately caused their injuries. Plaintiffs have not come forward with any evidence that creates a genuine issue of material fact about whether the injuries for which they seek recovery were proximately caused ***by their reliance*** on any false statement by a Manufacturer.

promotion on all prescription opioid sales nationwide. In particular, she provides a direct regression model that compares all "detailing"[5] contacts by manufacturer sales representatives (lumping all detailing of the named Manufacturers along with that of manufacturers that Plaintiffs opted not to sue) to the number of milligrams of morphine equivalent (MME) sales for all opioids at issue. (*Id.* ¶¶ 58–60.)

Based on an instruction from Plaintiffs' counsel, Rosenthal assumes that ***all*** opioid detailing from Manufacturers' sales representatives to prescribers was unlawful, regardless of the length, scope, substance, or impact of the detail on prescribing. (Ex. 1, Rosenthal Rep. ¶ 75; Ex. 2, Rosenthal Dep. Tr. 149:24–150:7.) But Plaintiffs do not even allege that all detailing was wrongful, nor could they credibly do so. There is no dispute that detailing and other promotions consistent with a medication's FDA-approved label are lawful and serve important functions. In particular, detailing helps inform prescribers of new treatment options and educate them about the medications' approved uses, risks, and benefits. Detailing may help increase sales, but, of course, there is nothing wrong with a manufacturer trying to increase sales via lawful promotion. *See, e.g.*, *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011) ("Speech in aid of pharmaceutical marketing … is a form of expression protected by the Free Speech Clause of the First Amendment."). In short, detailing is only actionable if it is misleading, but Rosenthal does nothing to distinguish between lawful and misleading detailing. As such, any testimony she might offer would provide no evidence about whether and to what extent any alleged ***deceptive*** marketing can be causally linked to Plaintiffs' alleged losses. And counsel's instruction is not proof that any

[5] "Detailing" means a sales representative's physical visit to a prescriber's office to convey information about the product in question—whether or not the sales representative speaks to the prescriber directly. (Ex. 1, Rosenthal Rep. ¶ 56; Ex. 2, Rosenthal Dep. Tr. 44:11-19.)

alleged marketing by a Manufacturer Defendant was unlawful, let alone that every visit to every doctor for decades was unlawful and had the exact same effect on sales. No such proof exists.

Equally important, Rosenthal's model did not analyze and thus cannot prove that any prescribers relied on Manufacturers' allegedly deceptive marketing (as opposed to other information about the medicines) when making their decisions to prescribe opioids. Rather, her analysis at most addresses the question "what would have happened if these manufacturers had not marketed their products" at all. (Ex. 2, Rosenthal Dep. Tr. 79:23-80:24; *see* Ex. 1, Rosenthal Rep. ¶ 11.) Furthermore, by her own admission, Rosenthal did not attempt to measure the number of improper, harmful, or medically unnecessary prescriptions written as a result of Manufacturers' alleged unlawful conduct. In fact, she clarified that she was not asked "to examine th[e] question about whether [any] prescription[s] … [were] medically unnecessary," and explained her view that "[t]he fact that the promotion was unlawful to me does not equate to the fact that a prescription was medically unnecessary." (Ex. 2, Rosenthal Dep. Tr. 150:8–153:5.) Rosenthal simply does not model the relevant question: whether and to what extent the alleged ***false*** marketing by any Manufacturer Defendant caused prescribers to write medically unnecessary/excess opioid prescriptions in Summit or Cuyahoga County.

Perhaps recognizing these flaws, Plaintiffs also attempt to have certain non-economists—Drs. Mark Schumacher (an anesthesiologist), Anna Lembke (a psychiatrist), and Katherine Keyes (an epidemiologist)—speculate on the causal effects of the marketing by Manufacturers based on their review of a few general studies about marketing.[6] But apart from lacking the necessary specialization to give such opinions, none of these proffered "experts" have evaluated any

[6] *See, e.g.*, Ex. 3, Keyes Rep. at 22; Ex. 4, Lembke Rep. at 4-6, 14-21, 32-33, 37, 58, 63, 66, 68-70, 73, 75-79, 97; Ex. 5, Schumacher Rep. ¶¶ 9, 58, 60, 82, 84. These experts' failures are disclosed more fully in a *Daubert* motion.

prescription data in Summit or Cuyahoga County. None has run any type of statistical analysis or surveyed any physicians in Summit or Cuyahoga County to understand why they wrote opioid prescriptions. And none even purports to offer any opinion on whether any particular prescriber in either County relied upon ***any*** marketing by any of the Manufacturer Defendants to write an opioid prescription—much less one that was medically unnecessary or harmful. In fact, Keyes did not even review ***any*** marketing by any of the Manufacturers.[7] As a result, these stray causation opinions are nothing more than gross speculation and should be excluded as a matter of law—yet, even if they are admitted, they certainly do not come close to meeting Plaintiffs' causation burden.

*2. Plaintiffs Cannot Prove Any Manufacturer's Allegedly Fraudulent Marketing Caused Their Alleged Injuries.*

Even if Plaintiffs had evidence that some alleged marketing misconduct by some Manufacturers caused some medically unnecessary/excess prescriptions (as explained above, they do not), Plaintiffs still would be required to prove that these medically inappropriate/excess prescriptions proximately caused Plaintiffs' harms. For proof of this part of the causal chain, Plaintiffs rely solely on the analysis of another expert, David Cutler. Cutler's testimony is fundamentally flawed and should be excluded for the reasons explained in the accompanying *Daubert* motion. But even if it is admitted in its entirety, Cutler's testimony does not prove that any portion of the alleged opioid-related harms in the Track One Counties was caused by medically improper/excess prescriptions that resulted from any Manufacturer's false marketing.

Cutler was asked to estimate the percentage of opioid-related harms in the Track One Counties caused by Defendants' alleged misconduct. (Ex. 13, Cutler Rep. ¶ 8.) As a threshold matter, Cutler never answered that question, but instead provided an estimate of ***all*** opioid-related

[7] Ex. 6, Keyes Dep. Tr. 457:8-10.

harms in the Track One Counties—including those caused by Chinese fentanyl, heroin, and other illicit opioid drugs. Cutler then performed regression analyses that purportedly identified the harms caused by the "average" prescription opioid shipments (not just Defendants', and not just those Plaintiffs' claim were unlawful). Specifically, his "direct model" analyzed the correlation between the total quantity of prescription opioids shipped (by all distributors, not just Defendants) across a 400-county sample (not just the Track One Counties) and changes in mortality from all opioids (including illegal ones that Defendants had nothing to do with, like heroin and fentanyl). His "indirect model" assumed that increases in opioid deaths are Defendants' fault if he cannot explain the increases using far-from-comprehensive economic and demographic indicators from within the same national 400-county sample. (*Id.* ¶ 26.) Cutler's analyses simply ignore the numerous intervening and superseding causes (doctors, pill mills, criminal distribution, criminal diversion, and criminal consumption) between the alleged unlawful conduct by Manufacturers and opioid mortality from illegal opioids as well as from medically necessary and allegedly unnecessary prescription opioids.

Cutler's analyses are incapabale of connecting Manufacturers to Plaintiffs' alleged injuries, both because he does not focus his analysis on Manufacturers' alleged misconduct and because his regression models do not analyze the harms Plaintiffs allege. First, as explained, Cutler lumps together the increase in mortality caused by legal medications and illegal drugs as well as the effects of medically necessary and allegedly unnecessary prescriptions. To isolate the effects of the alleged misconduct, Cutler claims that he can simply multiply his flawed "average shipment" estimate by Rosenthal's estimates of prescriptions caused by detailing. (*Id.* ¶¶ 58-75.) But for the reasons noted above, Rosenthal's analyses cannot create that necessary link between alleged misconduct and harms because she does not (1) isolate what percentage of opioid prescriptions are

linked to any unlawful versus lawful conduct, (2) identify any medically inappropriate/excess prescriptions, or (3) link any prescriptions resulting from detailing to any harms in Summit or Cuyahoga County.

Second, Cutler's direct model measures only the relationship between all prescription opioid shipments—which is not the alleged misconduct—and all opioid mortality from all opioids—which is not Plaintiffs' alleged harm. And Cutler even admits that the relationship between all prescription opioid shipments and all opioid mortality in 400 counties across the country is not a good proxy for the disparate set of harms (*e.g.*, costs associated with juvenile removals and addiction treatment) for which the Track One Counties seek to recover. (Ex. 14, Cutler Dep. Tr. 533:20–534:5.) For those reasons alone, his models provide no evidence that Manufacturers' alleged misconduct proximately caused Plaintiffs' alleged harms.

Third, even assuming all opioid mortality was a good proxy for Plaintiffs' alleged harms (it is not), Cutler's analyses do not address whether Defendants' (collective or individual) opioid shipments in Cuyahoga or Summit County had the "average impact" on mortality in Cuyahoga or Summit that he calculates for all opioid prescription shipments in 400 counties across the country. Thus, there is no input he can apply to his "average shipment" percentage to link the mortality (or any other harms) he analyzes to Manufacturers' (collective or individual) shipments, let alone alleged shipments resulting from misconduct.

### B. Plaintiffs Have No Evidence That Any Manufacturer's Alleged Diversion-Control Failures Proximately Caused Their Alleged Injuries.

To establish proximate cause for their claims predicated on Manufacturers' purported failure to control the distribution of prescription opioids (Counts 2, 4, 5-11), Plaintiffs must present four layers of evidence. First, they must actually produce evidence of each individual Manufacturer's diversion-control failures. Second, Plaintiffs must show that such failures caused

excess shipments of each Manufacturer's prescription opioids into Summit and Cuyahoga Counties. Third, they must show that these "excess" shipments were in turn diverted for non-medical use. And finally, Plaintiffs must demonstrate that these diverted medications caused them direct harm.

*1. Plaintiffs Have No Evidence That Any Manufacturer's Alleged Diversion-Control Failures Caused Excess Prescriptions in the Track One Counties.*

Plaintiffs make no effort to prove the second and third prongs of this analysis. They offer experts who purport to opine that each Manufacturer's SOM programs was deficient, and abatement experts who purport to opine about Plaintiffs' claimed harm. And they offer experts who supply testimony that ***distributors*** shipped "excess" orders into these jurisdictions. But fatally, Plaintiffs simply skip the middle steps for Manufacturers.

Plaintiffs proffer the testimony of three different experts—Craig McCann, Lacey Keller, and James Rafalski—in their attempt to connect potentially suspicious transactions to individual Manufacturers. But McCann and Keller look only at shipments ***between distributors and pharmacies***, not orders shipped by any Manufacturer to a distributor that the Manufacturer actually had power to halt. Moreover, neither McCann, Keller, nor Rafalski identifies "suspicious orders" that a Manufacturer (or even Manufacturers collectively) shipped as a result of the alleged distribution-control failures. Thus, there is no dispute of material fact that any Manufacturer's distribution-control failures (or even Manufacturers' alleged distribution-control failures collectively) proximately caused excess shipments to be distributed into Cuyahoga or Summit County, let alone that such excess shipments caused harm Plaintiffs' alleged harms. Taking ***all*** of Plaintiffs' expert opinions as true, all that exists is a list of transactions between distributors and pharmacies that might or might not be "suspicious" depending on which of the experts' 21 separate definitions you use. Critically, however, none of Plaintiffs' experts opine that ***any*** of the 21

versions of their metrics are appropriate or required under the CSA. Plaintiffs' experts have no opinion about which of the sales from distributors or pharmacies flagged by these varying metrics were "suspicious" (if any), which of the "suspicious" orders were appropriate to ship and which should not have been shipped and were therefore "excessive" (if any), and whether any "excessive" shipments caused any harm in these Counties. Even taking all of Plaintiffs' expert testimony as true, the trier of fact will be presented with zero evidence supporting a finding that any such shipments caused harm individually or in the aggregate.

***McCann's Analysis Of Distributor Shipments To Pharmacies Cannot Establish Causation With Respect To Manufacturers.*** McCann takes five compliance metrics provided by Plaintiffs' counsel and applies them to ***distributor shipments to pharmacies***—not to any Manufacturer's shipments. (Ex. 7, McCann Dep. Tr. 136:1-7; Ex. 8, McCann 3/25/2019 Rep. ¶¶ 15, 28, App'x 6.) McCann then identifies the sales from ***distributors to pharmacies*** that would be flagged under Plaintiffs' counsel's five compliance metrics. Although McCann identifies the distributor shipments to pharmacies flagged by these metrics, he does not opine that any Manufacturer shipped an excess order into the Track One Counties. McCann offers no opinion about which of the five metrics he applies, if any, is an appropriate or legally required metric for suspicious order monitoring. (Ex. 7, McCann Dep. Tr. 127:18–129:15.) More importantly, McCann himself disavows that he would offer any testimony regarding which distributor-pharmacy shipments were suspicious, confirming that he does "not tak[e] the opinion that a flagged transaction is necessarily a suspicious order" or "that a flagged transaction is necessarily illegal or representative of illegal conduct." (*Id.* at 149:17–150:4.) McCann put it best himself: "I'm just serving as a calculator." (*Id.* at 129:15.) Given that he is merely a calculator for data concerning ***distributor sales to pharmacies***, McCann certainly cannot offer evidence that would raise a

disputed issue of material fact as to whether any ***Manufacturer's*** sales or distribution-control failures caused any (let alone a "flood of") medically improper/excess opioid prescriptions or diversion in the Track One Counties.

Plaintiffs engaged a separate expert, James Rafalski, who opines that the orders from ***distributors to pharmacies*** flagged by McCann are allegedly suspicious orders and ***should not have been shipped by distributors***. (*See, e.g.*, Ex. 9, Rafalski Rep. at 69.) However, like McCann, Rafalski makes no such claim about any Manufacturer shipment. Indeed, Rafalski admitted in his deposition that he was not offering any opinion that any particular order shipped by a Manufacturer into Summit County or Cuyahoga County was, in fact, suspicious. (Ex. 10, Rafalski Dep. Tr. 635:2-13; 823:8-824:8. ("A: I do not identify any single suspicious order – any order specifically that was suspicious.")). Put simply, there is no expert in this case who can offer evidence that Manufacturer Defendants could have or should have stopped any suspicious orders from entering these Counties.

***Keller's Analysis Of Distributor Shipments To Pharmacies Cannot Establish Causation With Respect To Manufacturers.*** Keller applies sixteen separate compliance metrics (none required by DEA) to a different source of data reflecting shipments between distributors and pharmacies—again, not any Manufacturer Defendant's shipments. (Ex. 11, Keller Dep. Tr. 88:13-22, 90:10-17, 96:9-17.) Based on those metrics, she identified orders that flagged one or more of these sixteen compliance metrics. But, like McCann, Keller confirmed that she cannot opine whether any Manufacturer should have used any of these metrics (*id.* at 50:14-25), whether any order identified by those metrics should have been reported to the DEA (*id.* at 55:23–56:19), or whether any such orders ***were even suspicious*** (*id.* at 51:6–52:15). And her testimony about orders that she does not identify as "suspicious" cannot prove that any of the Manufacturer Defendants

actually shipped suspicious orders, much less that Manufacturers shipped suspicious orders that resulted in "excess" opioid prescriptions in the Track One Counties.

Given Keller's and McCann's inability to opine on any actual orders shipped by Manufacturers, including in the Track One Counties, Plaintiffs rely upon Rafalski's and Seth Whitelaw's generic critiques of Manufacturers' suspicious order monitoring and anti-diversion programs. These opinions are plagued by the same fundamental flaw, however, as those of McCann and Keller. While Rafalski claims to analyze Manufacturers' compliance programs, he admits that he cannot identify any suspicious orders shipped by a Manufacturer that shouldn't have been shipped, much less one that ended up in Summit County or Cuyahoga County. (Ex. 10, Rafalski Dep. Tr. 635:2-13.) Similarly, while Whitelaw criticizes Mallinckrodt's controlled substances compliance program, he is not offering an opinion as to "whether any particular order was diverted or not diverted" and does not offer an opinion as to whether any Mallinckrodt product was diverted. (Ex. 12, Whitelaw Dep. Tr. 836:4-837:14).

Lacking evidence that Manufacturer Defendants (collectively or individually) failed to investigate, report, or halt ***any*** suspicious orders, Plaintiffs cannot establish that the alleged diversion-control failures caused medically unnecessary/excess prescriptions in Cuyahoga or Summit County.

*2. Plaintiffs Cannot Prove Any Manufacturer's Alleged Diversion-Control Failures Caused Their Alleged Injuries.*

Plaintiffs distribution-control claims fail for the independent reason that—unlike with distributors and pharmacies—Cutler does not even attempt to estimate the impact of any Manufacturer's (or even the collective Manufacturers') alleged failures related to suspicious order

monitoring or diversion control.[8] Nor does any other Plaintiffs' expert. Because Cutler is Plaintiffs' only expert who purports to translate the impact of Manufacturers' unlawful conduct into harms in Plaintiffs' jurisdictions, Plaintiffs offer ***no evidence*** of a causal connection between any allegedly suspicious orders shipped ***by Manufacturers*** and Plaintiffs' alleged harms. That should end the inquiry on all claims against Manufacturers to the extent they are based on diversion-control failures. At an absolute minimum, this Court should order summary judgment on all such claims because Plaintiffs cannot establish that any Manufacturer's alleged failure to maintain effective diversion controls caused their claimed injuries.

### C. Plaintiffs' Lumping Together Of All Manufacturers Prevents Plaintiffs From Proving Proximate Causation Against Any Individual Manufacturer.

Plaintiffs also fail to prove proximate cause for the independent reason that their aggregate proof models do not even attempt to prove that ***each Manufacturer's*** unlawful conduct proximately caused their harms. The burden to prove proximate cause against each individual defendant does not disappear simply because a case involves multiple plaintiffs, municipal entities, or multiple defendants.

Indeed, for Plaintiffs' claims for damages asserted against Manufacturers individually—*i.e.*, all claims except conspiracy—Plaintiffs must prove that the specific conduct of ***each Manufacturer*** proximately caused each of their injuries. *See, e.g.*, *Pang v. Minch*, 559 N.E.2d 1313, 1324 (Ohio 1990) ("the burden of proof is upon the plaintiff to demonstrate that the conduct of ***each defendant*** was a substantial factor in producing the harm" (emphasis added)); *Volbers-*

[8] S*ee* Ex. 13, Cutler Rep. App'x J. And Cutler confirmed that "Appendix II.J: Framework for Estimating Harms Due to Distributor Misconduct"—his modeling of purported controls failures to harm in Plaintiffs' jurisdictions—"is not looking at any single defendant. It's merely showing how to take an estimate of distributors'—in this case an estimate that was provided to me of ***distributors' misconduct*** and calculate the harms that result from that. And nothing in Appendix J is specific to any single defendant." Ex. 14, Cutler Dep. Tr. 602:23–603:6 (emphasis added). There is no comparable analysis for Manufacturers' alleged distribution misconduct.

*Klarich v. Middletown Mgt., Inc.*, 929 N.E.2d 434, 440 (Ohio 2010) (fraud claims require "injury proximately caused by the" plaintiff's "justifiable reliance" on the defendant's fraudulent statements); *Beck v. Edward D. Jones & Co.*, No. 85-1292, 1990 WL 120745, at *1 (C.D. Ill. May 8, 1990) ("It is clear that to state a RICO cause of action against a defendant each element must be established as to each defendant.").

As a matter of law, Plaintiffs cannot satisfy this burden by (1) aggregating the conduct of Manufacturer Defendants and attempting to show that, viewed collectively, their alleged misconduct caused Plaintiffs' injuries; and (2) then declaring that each Manufacturer must therefore be liable. Indeed, in rejecting the market-share theory of liability, the Ohio Supreme Court insisted that a "plaintiff must establish a causal connection between the defendant's actions and the plaintiff's injuries, which necessitates identification of the particular tortfeasor." *Sutowski v. Eli Lilly & Co.*, 696 N.E.2d 187, 190 (Ohio 1998). The idea that "[m]anufacturers are required to pay or contribute to payment for injuries which their product may not have caused … is not the law in Ohio." *Id.* (internal quotation marks and citation omitted); *see also Kurczi v. Eli Lilly & Co.*, 113 F.3d 1426, 1432 (6th Cir. 1997) (Ohio Products Liability Act "embodies the general common law principle that a plaintiff has to prove an injury proximately caused by a particular defendant."); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, MDL No. 1699, 2012 WL 3154957, at *4 (N.D. Cal. Aug. 2, 2012) ("A plaintiff has standing to sue under section 1964(c) only if the defendant's RICO violation proximately caused the plaintiff's injury."). Yet, Plaintiffs cannot point to any evidence tying the alleged misconduct of any single Manufacturer to their alleged injuries. Indeed, both Rosenthal and Cutler readily admit that they do not even attempt to analyze the impact of any individual Manufacturer's alleged unlawful conduct.[9]

[9] The fraud-on-the-market theory is also improper under RICO. *See, e.g.*, *Lawrie v. Ginn Dev. Co.*, No. 3:09-cv-446-J-32JBT, 2014 WL 4788067, at *14 (M.D. Fla. Sept. 19, 2014) (dismissing RICO claim where plaintiffs' alleged

Rosenthal expressly concedes her models are "not designed to assign liability to individual manufacturers" (Ex. 2, Rosenthal Dep. Tr. 164:4-9)—the very question her testimony must address for all of Plaintiffs' non-conspiracy claims. *See, e.g.*, *Pang*, 559 N.E.2d at 1324; *Sutowski*, 696 N.E.2d at 190 (plaintiff must prove proximate cause between each defendant's unlawful conduct and plaintiff's asserted injuries). Instead, as Rosenthal admitted at her deposition, her models "only look[ ] at aggregate effects." (Ex. 2, Rosenthal Dep. Tr. 194:13-14.) That is, "total marketing [versus] total sales" for all opioid manufacturers "at the national level." (*Id.* at 122:22-23.) And her model does not allow disaggregation by medication, by Manufacturer, by detailing content, by detailing duration, or by any other basis—it simply looks at all detailing, by everyone (including manufacturers not named as defendants). (*See, e.g.*, *id.* at 196:10-25; 202:3-12; 204:15-205:25; 201:12–211:2; 332:1-24; 344:3-6.)

Likewise, Cutler repeatedly conceded that he did not even attempt to analyze the harms caused by any particular Manufacturer:

- "The analysis presented here does not attempt to uniquely apportion harm resulting from actions by any individual type of defendant." (Ex. 13, Cutler Rep. ¶ 31.)
- "[My model] is attributing the harm to the defendants as a whole. It is not attributing it to any specific defendant. And there is nothing in this report that says in order to attribute it to a specific defendant, follow the following procedure." (Ex. 14, Cutler Dep. Tr. 68:14–69:3.)
- "I made no attempt to calculate the proportion of fault due to any individual defendant." (*Id*. at 57:12-16.)
- "I have not done anything with respect to any specific defendant." (*Id*. at 68:12-13.)
- "[My model] does not rely upon any specific delineation as to who it was that caused the harm." (*Id*. at 73:12-24.)

injury "rel[ied] on a fraud-on-the-market theory"); *In re Schering–Plough Corp.*, No. 2:06-cv-5774 (SRC), 2009 WL 2043604, at *20 (D.N.J. July 10, 2009) (noting that the fraud on the market theory of injury "has been resoundingly rejected outside the context of federal securities fraud litigation" and "is not cognizable under RICO"); *Haley v. Merial, Ltd.*, 292 F.R.D. 339, 356 n.11 (N.D. Miss. 2013) ("Because the "fraud on the market" theory is cognizable only in the context of securities litigation, the theory cannot be used to prove causation in a RICO action").

Thus, Cutler too does not—and cannot—offer any opinions about whether any particular Manufacturer caused any of the harms he attributes to Defendants as a whole.

### D. Courts Have Rejected Far Simpler Aggregate Proof Models Than The Ones Plaintiffs Seek To Use Here.

Courts throughout the country have rejected plaintiffs' efforts to try to prove through expert testimony, including an aggregate regression model, that a defendant's false marketing of a prescription medication caused medically unnecessary/excess prescriptions. And those courts have done so in cases where the chain of causation was far simpler—namely, where third-party payors asserted RICO claims against a single drug manufacturer based on off-label promotion of a particular medication. The rationale behind these decisions applies with even more force here given that Plaintiffs do not aggregate the conduct of just a single manufacturer. Instead, they engage in an unprecedented lumping of the conduct of multiple different Manufacturers, multiple types of medicines, and multiple diverse and varied marketing practices, purporting to identify a single, uniform "impact." This approach cannot prove proximate causation as a matter of law.

For example, the Seventh Circuit, joining the Second, Ninth, and Eleventh Circuits, recently rejected third-party-payors' assertion that they could "estimate the effects of [the defendant's] promotion by using a[n] [aggregate] regression analysis" and therefore prove their damages caused by a particular manufacturer's unlawful off-label promotion of a particular medication. *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 873 F.3d 574, 577 (7th Cir. 2017). As the court explained, a regression model could not account for off-label prescriptions that were "beneficial to patients," and "[i]t would not be proper to calculate damages by assuming that all off-label prescriptions are improper." *Id.* Moreover, any workable aggregate regression model would have to account for other potential causes by "[d]isentangling the effects of the

improper promotions from the many other influences on physicians' prescribing practices," which "would be difficult" even if theoretically possible. *Id.*

As the Second Circuit similarly explained, "it is possible … to envision a drug so dangerous that no physician would ever prescribe it to treat a non-fatal condition if that physician were aware of its true risks," but absent such an extreme circumstance, expert analysis is generally incapable of demonstrating causation given "the multitude of factors" that "enter[] into individual physicians' prescribing decisions." *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 92 (2d Cir. 2015). In *Sergeants*, Rosenthal's testimony about the statistical "decline in [the drug's] sales" after a corrective disclosure was insufficient to support any inference that all pre-disclosure prescriptions were caused by the misrepresentation because Rosenthal "simply 'assumed' that a downturn in [the drug's] sales was attributable to the disclosure of the previously hidden safety risks." *Id.* "[C]orrelation does not demonstrate causation," and plaintiffs failed to control for numerous other correlated factors. *Id.*

For this reason, the majority of courts to address whether prescribers' reliance on fraudulent marketing can be proven through aggregate or general proof have held that it cannot. *See, e.g.*, *In re Bextra*, 2012 WL 3154957, at *7 ("Because 'at least some doctors were not misled by Defendants' alleged misrepresentations … general proof of but-for causation is impossible.'" (quoting *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 135 (2d Cir. 2010))).[10] That principle applies here, too.[11]

[10] *See also In re Vioxx Prod. Liab. Litig.*, MDL No. 1657, 2010 WL 11570867, at *7 (E.D. La. 2010) ("In this case … it is not sufficient for Plaintiff to generally assert that Merck's misrepresentations led to the prescription of Vioxx. Each decision by each doctor and each patient was different."); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, MDL No. 2100, 2010 WL 3119499, at *7 (S.D. Ill. 2010); *Ironworkers Local Union No. 68 v. AstraZeneca Pharm. LP*, 585 F. Supp. 2d 1339, 1344 (M.D. Fla. 2008); *accord In Southeast Laborers Health & Welfare Fund v. Bayer Corp.*, 655 F. Supp. 2d 1270, 1281 (S.D. Fla. 2009) ("Doctors are presumed to go beyond [the] advertising . . . .").

[11] *In re Neurontin Marketing and Sales Practices*, 712 F.3d 21 (1st Cir. 2013), is an outlier and irrelevant for the same reasons. While Manufacturers disagree with *Neurontin*'s reasoning, it has no application here in any event. The

Critically, Plaintiffs' failures here are even more pronounced. First, because their experts measure only the purported effects of ***all*** opioids, Plaintiffs are seeking to hold Manufacturers liable for the effects of street drugs like heroin and illicit fentanyl. No court anywhere has held the manufacturer of a lawful product liable for harms flowing from the use of illegal products that the manufacturer had nothing to do with.

Second, Plaintiffs' experts' models do not just attempt to aggregate an individual Manufacturer Defendant's allegedly fraudulent promotion to show that Manufacturer Defendant's conduct caused Plaintiffs' harm. Rather, as Rosenthal explained, "[t]here are two levels of aggregation [in her analysis]. One is from the doctors up to the total product level, and the other is from the product [of] the defendant to the whole class" of opioid products. (Ex. 2, Rosenthal Dep. Tr. 80:6-12.) Rosenthal thus attempts to model the relationship between nationwide detailing contacts for the entire opioid class for over two decades regardless of whether there was in fact anything false conveyed in the detailing because she was "interested in understanding how marketing as a whole drove sales in this market." (*Id.* at 80:16-18.) Plaintiffs have no evidence—from an expert or otherwise—that can prove which, if any, of the total opioid prescriptions nationwide that Rosenthal attributes to Manufacturers collectively were medically improper/excess (let alone whether the detailing of any Manufacturer Defendant caused a prescriber in the Track One Counties to write any such medically improper/excess prescription). (*See id.* at 150:8–153:5.)

causal chain that the plaintiffs' experts analyzed in *Neurontin* (similar to all the third-party-payor cases) was infinitely simpler than is Plaintiffs'. *Neurontin* involved Pfizer's off-label promotion of a single medication (Neurontin)—all of which was per se unlawful—over a discrete time in that drug's lifecycle on the market. Because the plaintiffs proved that Neurontin was medically ineffective for all of the promoted off-label uses, all of the prescriptions used in the model were per se excessive. *See id.* at 47. Thus, *Neurontin* at most stands for the proposition that expert analysis can evidence a causal relationship between unlawful marketing and medically unnecessary/excess prescriptions when the analysis successfully isolates the fraudulent promotion (on the one hand) and the medically unnecessary/excess prescriptions (on the other) and models the relationship between the two.

To be sure, although Plaintiffs' counsel instructed Rosenthal to assume that all detailing was unlawful, even Plaintiffs concede that not all opioid prescriptions—or even all opioids written after a prescriber received allegedly false marketing—were medically improper/excess. (*See, e.g.*, Ex. 5, Schumacher Rep. ¶¶ 86-88.) In short, Rosenthal's testimony cannot serve as evidence that any Manufacturer's false marketing caused opioid prescriptions that should not have been written, which in turn caused Plaintiffs' harms, because she did not analyze either of those relationships.

Because Plaintiffs' expert evidence is insufficient to prove any individual Manufacturer proximately caused the alleged harms in the Track One Counties—the relevant question for all of their non-conspiracy claims for damages—Plaintiffs cannot prove these claims as a matter of law.

### E. Plaintiffs' Failure To Prove Causation Individually Applies Equally To Their Public Nuisance Claim For Abatement Costs.

Plaintiffs cannot avoid the burden to prove Manufacturer-Defendant-specific causation by asserting an absolute common law public nuisance claim for abatement costs (Count 6). Just as Plaintiffs must prove that the conduct of each Manufacturer proximately caused each of their injuries to recover damages, Plaintiffs must prove that ***each Manufacturer*** proximately caused the nuisance to recover abatement costs. *See, e.g.*, *City of Cincinnati v. Beretta U.S.A., Corp.*, 768 N.E.2d 1136, 1147-49 (Ohio 2002); *City of Cincinnati v. Deutsche Bank Nat'l Trust Co.*, 863 F.3d 474, 477 (6th Cir. 2017); *Cleveland v. JP Morgan Chase Bank, N.A.*, No. 98656, 2013 WL 1183332, at *3 (Ohio Ct. App Mar. 21, 2013); *see also People ex rel. Spitzer v. Sturm, Ruger & Co.*, 309 A.D.2d 91, 103-04 (N.Y. App. 2003); Restatement (Second) of Torts § 834 cmt. d (1979) ("When a person is only one of several persons participating in carrying on an activity [that causes the nuisance], his participation must be substantial before he can be held liable for the harm resulting from it. This is true because to be a legal cause of harm ***a person's conduct must be a substantial factor*** in bringing it about." (emphasis added)).

Thus, the only difference between Plaintiffs' burden to show proximate cause for purposes of their public nuisance claim for abatement costs and their claims for damages against Manufacturers individually is that the causal link must be established between each Manufacturer's unlawful conduct and the public nuisance, as opposed to Plaintiffs' injuries. As explained above, Rosenthal and Cutler concede that they do not attempt to measure the effects of any Manufacturer's alleged misconduct. Rather, they consider Manufacturers' alleged misconduct and the resulting effects only in the aggregate. But Plaintiffs apparently contend that the public nuisance consists of negative externalities experienced in their jurisdictions—*i.e.*, the same harms that gave rise to their injuries for damages purposes. (*See* Ex. 15, McGuire Public Nuisance Rep. ¶ 16 ("[P]ublic nuisance, in economic terms, is generally observed when an action (or set of actions) undertaken by a party (or group of parties) gives rise to overwhelming 'negative externalities.'"); *id.* ¶¶ 40-60). Accordingly, for all the same reasons that Plaintiffs cannot prove that the unlawful conduct of any individual Manufacturer Defendant proximately caused their alleged injuries, they likewise cannot prove that the conduct of any individual Manufacturer proximately caused whatever nuisance they allege. *See, e.g.*, *Beretta*, 768 N.E.2d at 1147-49; *Sturm*, 309 A.D.2d at 103-04.[12]

### F. Plaintiffs' Conspiracy Claims Do Not Absolve Their Failure to Prove Causation.

Alleging a conspiracy does not allow Plaintiffs to prove proximate cause by treating ***all conduct*** by ***all Defendants*** as one, either. Only the acts of co-conspirators can be treated collectively, and "[t]he damages must 'proximately result' from 'acts committed pursuant to a formed conspiracy.'" *Lawyers Title Co., LLC v. Kingdom Title Sols., Inc.*, 592 F. App'x 345, 355

[12] *See* Manufacturer Defendants' Mot. for Summ. J. on Plaintiffs' Public Nuisance Claims.

(6th Cir. 2014) (quoting *Minarik v. Nagy*, 193 N.E.2d 280, 281 (Ohio Ct. App. 1963)). Thus, the injury "cannot be the result of just any tort committed by a conspirator, or just any act committed in furtherance of the conspiracy." *Gosden v. Louis*, 687 N.E.2d 481, 497 (Ohio Ct. App. 1996). The plaintiff's injury "must have been caused by a tort [or torts] committed in furtherance of the conspiracy," *i.e.*, the predicate acts. *Id.* The same is true for RICO conspiracy claims, except that harm must be caused by the collective racketeering activities of the co-conspirators committed in furtherance of the conspiracy. *See Beck v. Prupis*, 529 U.S. 494, 505-06 (2000). Accordingly, the relevant question in Plaintiffs' conspiracy claims is still whether the predicate acts committed by co-conspirators in furtherance of the conspiracy—and only those acts—proximately caused each of Plaintiffs' injuries.

***RICO Marketing Conspiracy Claims.*** Plaintiffs allege that Purdue, Cephalon, Janssen, Endo, and Mallinckrodt (the "RICO Marketing Defendants," a subset of the Manufacturer Defendants) conspired to violate RICO through an "Opioid Marketing Enterprise" that used so-called front groups, key opinion leaders (KOLs), continuing medical education (CMEs) programs, and unbranded marketing to disseminate false information about the safety and efficacy of opioids. (ECF No. 1466, Summit 3AC ¶ 880.) Thus, for their claims asserting a conspiracy to violate RICO through an alleged Opioid Marketing Enterprise, Plaintiffs must prove that the racketeering activities of the RICO Marketing Defendants in furtherance of that conspiracy proximately caused their injuries. Yet none of Plaintiffs' experts isolate (or has the ability to isolate) the alleged racketeering activities of the RICO Marketing Defendants committed in furtherance of the alleged Opioid Marketing Enterprise.

Again, Rosenthal analyzes only the relationship between ***all*** nationwide in-person detailing contacts by ***all*** opioid manufacturers and nationwide opioid prescriptions for all opioid

medicines—not just Manufacturer Defendants', and certainly not just the RICO Marketing Defendants'. Completely absent from her opinion (or any other expert's) is any suggestion of a causal link between the alleged conduct going to the heart of the alleged conspiracy—that is, work with front groups, KOLs, CME programs, and unbranded marketing. Likewise, Cutler attempted to estimate the opioid-related harms in the Track One Counties caused by all shipments of prescription opioids without limiting his analysis in any way to the RICO Marketing Defendants, let alone to the alleged racketeering activities.

Neither the testimony of these experts nor any other expert Plaintiffs have offered can prove that the predicate acts of the RICO Marketing Defendants caused Plaintiffs' alleged injuries.

***RICO Supply Chain Conspiracy Claims.*** Similarly, Plaintiffs allege that Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen (the "RICO Supply Chain Defendants," a different subset of Manufacturer Defendants together with certain distributors) conspired to violate RICO through an "Opioid Supply Chain Enterprise" bent on flooding the market with opioids. (ECF No. 1466, Summit 3AC ¶ 909.) Thus, for their claims asserting a conspiracy to violate RICO through a supply-chain enterprise, Plaintiffs must prove that the racketeering activities of the RICO Supply Chain Defendants in furtherance of that conspiracy proximately caused their injuries. But like Plaintiffs' RICO marketing conspiracy claim, the RICO supply-chain conspiracy claim falls apart because Plaintiffs' experts do not isolate the conduct of RICO Supply Chain Defendants.

Once again, Cutler did not (and could not, based on his flawed approach) isolate the conduct of RICO Supply Chain Defendants, much less only the alleged racketeering activities of RICO Supply Chain Defendants committed in furtherance of the alleged Opioid Supply Chain Enterprise. Just as participation with so-called front groups and KOLs is critical to the RICO

Marketing claims, lobbying, participation in trade associations, and not reporting other alleged co-conspirators' distribution-control failures are critical conduct going to the heart of the Opioid Supply Chain Enterprise. But Plaintiffs' experts' analyses do not address these activities at all.

***Civil Conspiracy Claim.*** Plaintiffs' civil conspiracy claim against all Defendants (including Manufacturer Defendants) likewise requires proof that the tortious acts of all Defendants committed in furtherance of the alleged conspiracy proximately caused their harms. But Plaintiffs make no attempt to (and cannot) prove that their injuries were "caused by the underlying tort (or torts) necessary to support the claim for civil conspiracy." *Gosden*, 687 N.E.2d at 497. At best, Plaintiffs' expert evidence attempts to connect alleged unlawful marketing and alleged diversion-control failures to Plaintiffs' injuries with no regard as to how all of those alleged acts were committed as part of a grand conspiracy by each and every one of the Defendants—and they miss the mark widely at that. Plaintiffs offer no evidence to connect purportedly tortious conduct committed in furtherance of an all-encompassing conspiracy (and no other conduct) to their harms.[13]

## CONCLUSION

For the foregoing reasons, the Court should grant Manufacturer Defendants' motion for summary judgment for Plaintiffs' failure to offer proof of causation.

[13] *See* Manufacturers' Joint Mot. for Summ. J. on Plaintiffs' RICO, OCPA, and Conspiracy Claims.

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Respectfully submitted,

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[14] Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their pending motions to dismiss for lack of personal jurisdiction; they are specially appearing to join this motion as a result of the Court's deadline to file dispositive and Daubert motions, and, thus, they do not waive and expressly preserve their pending personal jurisdiction challenges.

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that the foregoing was served upon all counsel of record via email.

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